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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,485	04/18/2000	Claude Singer	1662/49502	2266

26646 7590 03/13/2002

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER
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HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

12

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/552,485

Applicant(s)

SINGER ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

**DETAILED ACTION**

1. Claims 29-45 are pending.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as anticipated by van der Burg et al (US Pat. No. 4,062,848) or, in the alternative, under 35 U.S.C. 103(a) as obvious over van der Burg'848. Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Van der Burg et al (US Pat. No. 4,062,848). Van der Burg et al. teaches the pharmaceutical formulation of mirtazapine compounds on column 1 (line 7).

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Water solutions are one of the known formulations for pharmaceutical composition.

Applicants claim pharmaceutical compositions of mirtazapine adduct that is the same as Van der Burg et al. Since an adduct of mirtazapine in aqueous solution is a pharmaceutical composition and would no longer be a water adduct of mirtazapine, the same material is obtained.

Claims 44 and 45 are alternatively rejected under 35 U.S.C. 103(a) as obvious over van der Burg'848. The cited reference teaches pharmaceutical formulations on column 1 (line 7). Applicants claim in the instant application water adduct of mirtazapine (a mixture of water and mirtazapine). Since water is one of the known compounds used as a pharmaceutical carrier, it would have been obvious at the time of the invention was made to the person having ordinary skill in the art to select water as a carrier to make pharmaceutical composition.

### ***Response to arguments***

Applicants arguments filed 02/19/2002 have been fully considered but they are not persuasive.

Applicants argue that an adduct of mirtazapine and water is chemically distinct from a water solution of mirtazapine. The examiner agrees with applicants that an adduct of mirtazapine and water is chemically distinct from a water solution of mirtazapine. However, the pharmaceutical composition in the form of a water solution of an adduct of mirtazapine and water is the same as a pharmaceutical composition in the form of water solution of mirtazapine itself. Whether the mirtazapine was in an adduct

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form or simply just mirtazapine, the pharmaceutical composition is the same regardless of the original form. The solution dissolves away the adduct. As far as we know the pharmaceutical formulations on column 1 (line 7) of van der Burg'848 is the same as an adduct of mirtazapine, because an adduct of mirtazapine in aqueous solution is a pharmaceutical composition and would no longer be a water adduct of mirtazapine. If applicants disagree, how could they distinguish between the two water solutions?

4. Claims 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Nickolson et al (US Pat. No. 5,977,099). Nickolson et al. recites in claim 1 (column 6, lines 9-11) "a combination comprising mirtazapine or a pharmaceutical acceptable salt thereof and at least on SSRI's or a pharmaceutically acceptable salt" that is embraced by the rejected claims. In the instant application, there has been recited in claim 44 "a pharmaceutical composition comprising a therapeutically effective amount" that is an open-end language. The phrase "comprising" is an open claim language and reads on all possible combination or composition of mirtazapine with other ingredients. Since applicant's pharmaceutical composition of mirtazapine compounds are the same as Nickolson et al., a 102(e) rejection is proper. Note previous rejection.

### ***Response to arguments***

Applicants arguments filed 02/19/2002 have been fully considered but they are not persuasive.

Please see the above response to arguments given for 102/103 rejection.

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5. Claims 29-43 are rejected under 35 U.S.C. 102(b) as being unpatentable over Kaspersen *et al.* Kaspersen *et al.* on page 1066 teaches crystallization of mirtazapine crude product from methanol/water to achieve colorless crystals. In claims 29-43, there has been recited an adduct of mirtazapine and the method of its preparation (precipitation from organic solvents such as alcohols). It appears to be the same process and therefore the products are presumed to be the same, i.e. inherently formed. See *In re Zelinski* 141 USPQ 217, *In re Best* 195 USPQ 432, and *In re Wiegand* 86 USPQ 155. Kaspersen teaches crystallization from methanol/water and the specification on page 10 (lines 3-10) discloses the crude product of mirtazapine is purified by recrystallization and also teaches a mixture of alcohol-water for solvent. Methanol/water that is used in Kaspersen is embraced by applicants alcohol-water. Also the processes (extraction, drying, and purification) on page 9 (lines 11-17) are the same as the Kaspersen's.

### ***Response to arguments***

Applicants arguments filed 02/19/2002 have been fully considered but they are not persuasive.

Applicants argue that Kaspersen does not disclose a method known to form an adduct of mirtazapine and water and does not disclose a method described in the specification to form an adduct. Applicants argue that the product disclosed in Kaspersen *et al.* is not inherently an adduct of mirtazapine and water. The examiner disagrees with applicants. According to MPEP 2112.01:

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*Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). [underscoring added]*

Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. Applicants can overcome the rejection over Kaspersen *et al.* by showing that their product is different from Kaspersen *et al.*

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36 and 42 recite "the adduct of mirtazapine and water ...containing up to about three weight percent water", but the said claims

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appear to be duplicates of claim 30. Whether a compound is precipitated from alcohol or any organic solvent, the final product is the same, as this is the only way to prepare.

***Response to arguments***

Applicants arguments filed 02/19/2002 have been fully considered but they are not persuasive.

Applicants argue that claims 36 and 42 are not duplicates of claim 30. The examiner disagrees with applicants. The specification does not teach that there are different products, just one. These it appears to be just one thing, and hence the claims all cover that same one thing. Since the specification teaches the same product, the rejection is proper.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

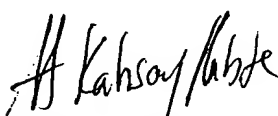
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**Conclusion**

¶ Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624

  
Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
March 12, 2002